

## REMARKS

Applicants acknowledge receipt of the Action dated 14 May 2008. Claims 6-19 and 29-30 are now pending in the application. Claims 1-5 and 20-28 are cancelled without prejudice. Minor amendments have been made to the specification to correct typographical errors, and minor amendments to Claims 18 and 19 were made to fix typographical errors. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

### REJECTION UNDER 35 U.S.C. § 102

Claims 6, 7, 27 and 28 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Vander Salm (U.S. Pat. No. 5,906,579). This rejection is respectfully traversed.

#### Claim 6

Claim 6 stands rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Vander Salm. At the outset, Applicants submit that the rejection of Claim 6 is rendered moot. Applicants amended Claim 6 to clarify that the catheter body and sheath body are capable of being mechanically pushed to advance the distal tip and that the system includes a magnet outside the body that applies a magnetic field to orient the distal tip of the catheter. These amendments of Claim 6 are supported by the specification as filed, at least at paragraph [0030]. These amendments thus render the rejection of Claim 6, under 35 U.S.C. § 102(b), moot for at least the following reasons.

Vander Salm does not expressly or inherently disclose each of the elements of amended Claim 6, and therefore, does not anticipate Claim 6. See MPEP 2131. Specifically, Vander Salm does not disclose, at the least, (1) a catheter body and the sheath body which are capable of being mechanically pushed to advance the distal tip; or (2) a magnet outside the body that applies a magnetic field to orient the distal tip of the catheter.

#### **(1) Vander Salm Does Not Explicitly or Inherently Disclose “the catheter body and the sheath body capable of being mechanically pushed to advance the distal tip.”**

Vander Salm does not disclose a catheter that is advanced by mechanical pushing. Rather, “it is noted [in Vander Salm] that by ‘flow directed’ applicant means

that the preferred balloon insertion process relies, at least in part, on the pressure of blood flow against the balloon to drive the balloon along, pulling the trailing catheter after it.” See Vander Salm, 6:14-18. Vander Salm further discloses a “light, flexible catheter capable of bending freely to follow the balloon when blood flow propels the partially inflated balloon along a turning path through the heart.” See Vander Salm, 6:22-25. Vander Salm’s light, flexible catheter does not describe a catheter body and sheath body which are capable of being mechanically pushed to advance the distal tip. Thus, Vander Salm fails to explicitly or inherently disclose a catheter body and sheath body that are capable of being advanced by mechanical pushing.

**(2) Vander Salm Does Not Explicitly or Inherently Disclose “a magnet outside the body that applies a magnetic field to orient the distal tip of the catheter.”**

Further, Claim 6 is directed to a system with a magnet *outside* the body that applies a magnetic field to *orient* the distal tip of the catheter. Claim 6 claims a catheter mechanically pushed, while the magnet outside the body applies a magnetic field that orients the distal tip. Vander Salm does not explicitly disclose a system with a magnet outside the body that applies a magnetic field to orient the distal tip of the catheter. Rather, Vander Salm discloses a catheter with a fragment or clip of magnetically *attractable* material to the balloon; a wand *inside* the body “pulls” or *attracts* the catheter to either hold it in place or pull the catheter once it has passed through the right ventricle. The use of magnetic attractive / repulsive forces to move or propel an object by a wand inside the body is not the same as the use of a magnetic field outside the body to merely orient the distal tip of the catheter. For example, a magnet held close to a compass that causes the compass needle to be attracted towards the magnet is very different from a magnet rotated above a compass to cause the compass needle to turn and align in the direction of a magnetic field of the magnet. Thus, Vander Salm does not explicitly disclose a magnet outside the body applying a magnetic field to orient the distal tip of a catheter as claimed in Claim 6.

Further, there is no basis or teaching in Vander Salm to reasonably support the determination that the reference device inherently discloses the system claimed in

Claim 6. As stated above, Vander Salm's catheter uses a wand inside the body and attraction forces to move the catheter or hold the catheter in place. Any attraction towards a magnet would interfere with the purpose of aligning a magnetically responsive element with a magnetic field direction that is changeable to a number of directions for facilitating orientation of the device, as claimed in Claim 6. While orienting the distal tip in a desired direction may constitute some movement, the catheter as claimed in Claim 6 is not being displaced or advanced through the body by the magnetic field. Since the whole point of Vander Salm is to attract a magnet tip to move the tip towards the wand inside the body or hold it in place, and attraction would interfere with the magnetic field orientation as claimed in Claim 6, Vander Salm does not teach or suggest or inherently disclose the system claimed in Claim 6.

Thus, Applicants submit that Vander Salm does not anticipate amended Claim 6. Reconsideration and withdrawal of the rejection of Claim 6 under 35 U.S.C. § 102 is respectfully requested.

#### Claim 7

Claim 7 stands rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Vander Salm. However, Vander Salm does not expressly or inherently disclose each of the elements of Claim 7, and therefore, does not anticipate Claim 7. See MPEP 2131. Specifically, Vander Salm does not disclose, at the least, "an energy source coupled to said distal tip for delivering therapeutic energy to a vessel occlusion" as claimed in Claim 7.

Further, Applicants submit that the rejection of Claim 7 is rendered moot. Applicants amended Claim 7 to include a magnet outside the body that applies a magnetic field to orient the distal end of the sheath, such that the catheter advances in a direction determined by the magnetic orientation of the distal end of the sheath. This amendment of Claim 7 is supported by the specification as filed, at least at paragraph [0030]. This amendment thus renders the rejection of Claim 7, under 35 U.S.C. § 102(b), moot as Vander Salm does not disclose, at the least, "a magnet outside the body that applies a magnetic field to orient the distal end of the sheath, such that the catheter advances in a direction determined by the magnetic orientation of the distal end of the sheath" as claimed in amended Claim 7.

**(1) Vander Salm Does Not Explicitly or Inherently Disclose “an energy source coupled to said distal tip for delivering therapeutic energy to a vessel occlusion.”**

Vander Salm’s “principal aspect” of the light source provided to the balloon catheter is “to serve as a visual aid to mark the location of the balloon at the catheter tip.” See Vander Salm, 6:63-66. The principal aspect disclosed in Vander Salm is to have a balloon perform the vessel occlusion, whereas, Claim 7 is directed to a system in which the energy source coupled to the distal tip delivers therapeutic energy to the vessel occlusion. Vander Salm further discloses that the light source may include an IR filter to avoid applying excessive heat, whereas, Claim 7’s energy source delivers therapeutic energy to a vessel occlusion. For these reasons alone, the rejection should be reconsidered and withdrawn, as Vander Salm does not inherently or explicitly disclose all of the elements of Claim 7.

**(2) Vander Salm Does Not Explicitly or Inherently Disclose “a magnet outside the body that applies a magnetic field to orient the distal end of the sheath, such that the catheter advances in a direction determined by the magnetic orientation of the distal end of the sheath.”**

As articulated more fully above in reference to Claim 6 (see Claim 6, Section (2)), Vander Salm does not disclose a magnetic outside the body or the application of a magnetic field to orient the distal end of the sheath as claimed in amended Claim 7. Rather, Vander Salm discloses a catheter with a fragment or clip of magnetically attractable material to the balloon; a wand *inside* the body “pulls” or *attracts* the catheter to either hold it in place or steer the catheter once it has passed through the right ventricle. Since the intent of Vander Salm is to *attract* a catheter to a wand *inside* the body for the sole purposes of holding the catheter in place or advancing the catheter into the right ventricle, Vander Salm fails to explicitly or inherently disclose, teach, or suggest a magnet *outside* the body that applies a magnetic field to *orient* the distal end of the sheath as claimed in amended Claim 7. Thus, Applicants submit that Vander Salm does not anticipate amended Claim 7. Reconsideration and withdrawal of the rejection of Claim 7 under 35 U.S.C. § 102 is respectfully requested.

### Claims 27 and 28

Claims 27 and 28 have been cancelled without prejudice, therefore, the rejection is rendered moot.

### REJECTION UNDER 35 U.S.C. § 103

Claims 8-10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Vander Salm (U.S. Pat. No. 5,906,579) in view of LeVeen (U.S. Pat. No. 4,154,246). Claims 11-12, 14-16, and 29-30 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Vander Salm in view of LeVeen and further in view of substitution of alleged known equivalents. Claims 13 and 18-19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Vander Salm in view of substitution of alleged known equivalents. Claim 17 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Vander Salm in view of Drasler (U.S. Pat. No. 5,370,609). These rejections are respectfully traversed.

### Claims 8-10

Claims 8-10 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the prior art as applied to Claim 6 above, and further in view of LeVeen. Claims 8-10 ultimately depend from Claim 6, which Applicants submit as patentable for at least the reasons stated above. Claims 8-10 are therefore submitted as patentable for at least the same reasons as stated for Claim 6. Furthermore, it would not have been obvious to modify the device of Vander Salm with the radio frequency heating allegedly disclosed in LeVeen, as Vander Salm does not disclose an energy source coupled to the metallic element to heat the metallic element. Vander Salm's "principal aspect" of the light provided to the balloon catheter is "to serve as a visual aid to mark the location of the balloon at the catheter tip." See Vander Salm, 6:63-66. Vander Salm further discloses that the light source may include an IR filter to *avoid applying excessive heat*, whereas, the remote radio frequency energy source as claimed in Claim 8 provides RF energy coupled to the metallic element to *heat* the metallic element. See Vander Salm, 7:52-55. Moreover, the Office Action does not even allege that the elements claimed in Claims 9 and 10 are disclosed or rendered obvious by the cited references. MPEP 2143.03 ("[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art"). For at least these reasons, the rejection of Claims 8-10

should be withdrawn, as the cited references do not disclose, teach or suggest the additional features required by them in combination with the other features recited in independent Claim 6 from which Claims 8-10 depend. Reconsideration and withdrawal of the rejection of Claims 8-10 under 35 U.S.C. § 103(a) are respectfully requested.

Claims 11-12, 14-16 and 29

Claims 11-12, 14-16 and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the prior art as applied to Claim 6 above, and further in view of LeVeen and further in view of substitution of alleged known equivalents. Claims 11-12, 14-16 and 29 ultimately depend from Claim 6, which Applicants submit as patentable for at least the reasons stated above. Claims 11-12, 14-16 and 29 are therefore submitted as patentable for at least the same reasons as stated for Claim 6. Furthermore, it would not have been obvious to modify the device of Vander Salm in view of LeVeen and allegedly known substitutions, as Vander Salm does not disclose an energy source to heat a thermally conductive element located proximate the distal tip or a heating element located proximate the distal tip adapted for coupling to a remote electrical energy source. Vander Salm's "principal aspect" of the light provided to the balloon catheter is "to serve as a visual aid to mark the location of the balloon at the catheter tip." See Vander Salm, 6:63-66. Vander Salm further discloses that the light source may include an IR filter *to avoid applying excessive heat*, whereas, the energy source as claimed in Claims 11 and 12 *heats* the thermally conductive element. See Vander Salm, 7:52-55. Moreover, the Office Action does not even allege that the elements claimed in Claims 12 and 29 are disclosed or rendered obvious by the cited references. MPEP 2143.03 ("[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art"). For at least these reasons, the rejection of Claims 11-12, 14-16 and 29 should be withdrawn, as the cited references do not disclose, teach or suggest the additional features required by them in combination with the other features recited in independent Claim 6 from which Claims 11-12, 14-16 and 29 depend. Reconsideration and withdrawal of the rejection of Claims 11-12, 14-16 and 29 under 35 U.S.C. § 103(a) are respectfully requested.

Claims 13 and 18-19

Claims 13 and 18-19 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the prior art as applied to Claim 6 above, and further in view of substitution of alleged known equivalents. Claims 13 and 18-19 ultimately depend from Claim 6, which Applicants submit as patentable for at least the reasons stated above. Claims 13 and 18-19 are therefore submitted as patentable for at least the same reasons as stated for Claim 6. For at least this reason, the rejection of Claims 13 and 18-19 should be withdrawn, as the cited reference does not disclose, teach or suggest the additional features required by Claims 13 and 18-19 in combination with the other features recited in independent Claim 6 from which Claims 13 and 18-19 depend. Reconsideration and withdrawal of the rejection of Claims 13 and 18-19 under 35 U.S.C. § 103(a) are respectfully requested.

#### Claim 17

Claim 17 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the prior art as applied to Claim 6 above, and further in view of Drasler. Claim 17 depends from Claim 6, which Applicants submit as patentable for at least the reasons stated above. Claim 17 is therefore submitted as patentable for at least the same reasons as stated for Claim 6. For at least this reason, the rejection of Claim 17 should be withdrawn, as the cited references do not disclose, teach or suggest the additional features required by it in combination with the other features recited in independent Claim 6 from which Claim 17 depends. Reconsideration and withdrawal of the rejection of Claim 17 under 35 U.S.C. § 103(a) are respectfully requested.

#### Claim 30

Claim 30 is rejected under 35 U.S.C. § 103(a) as being unpatentable over the prior art as applied to Claim 7 above, and further in view of LeVeen and further in view of substitution of alleged known equivalents. Claim 30 ultimately depend from Claim 7, which Applicants submit as patentable for at least the reasons stated above. Claim 30 is therefore submitted as patentable for at least the same reasons as stated for Claim 7. Furthermore, the Office Action does not even allege all of the elements claimed in Claim 30 are disclosed or rendered obvious by the cited references. MPEP 2143.03 ("[a]ll words in a claim must be considered in judging the patentability of that claim against the prior art"). For at least these reasons, the rejection of Claim 30 should be withdrawn, as

the cited references do not disclose, teach or suggest the additional features required by Claim 30 in combination with the other features recited in independent Claim 7 from which it depends. Reconsideration and withdrawal of the rejection of Claim 30 under 35 U.S.C. § 103(a) are respectfully requested.

**CONCLUSION**

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (314) 726-7505.

It is believed that the correct fees due are included with this filing. If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to change payment or credit any overpayment to Deposit Account No. **08-0750** for any additional fees required, particularly under 37 C.F.R. § 1.17(e).

Respectfully submitted,

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